

REMARKS

Reconsideration of this application is respectfully requested. To this end, petition is hereby made for a three-month extension of time to respond to the outstanding Office Action of August 25, 2008.

Claims 19-41 are pending in the application. Upon entry of this Amendment, claims 20-23, 27, 28 and 30 will be cancelled, claims 19, 24-26, 29 and 31-42 will be amended, and new claims 43-71 will be added.

In the outstanding Office Action, the Examiner rejected claim 40 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement of the U.S. patent statute, arguing that claim 40 requires a base material made from PTFE with a gas filler, while the specification only “enables” a gas filler used with Teflon. While the Examiner appears to be confusing the “enablement” requirement of the U.S. patent statute with the written description requirement, putting this aside, clearly Teflon is a well known trade name for poly(tetrafluoroethylene), as evidenced from the encyclopedia excerpts attached to this Amendment as Attachment A. As such, the specification of the present application has been amended to clarify that poly(tetrafluoroethylene) (“PTFE”), also known by the trade name TeflonTM, constitutes the base material. The specification has also been amended to correct the spelling of “SLE” as being

Systemic Lupus Erythematosus and to clarify the kinds of materials that are likely to have the problem of being broken down by the body. In view of the amendments to the application specification regarding Teflon™ being a brand name of PTFE, the Examiner's rejection of claim 40 under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Examiner has also rejected claims 26 and 37 under 35 U.S.C. §112, second paragraph, as being indefinite because claim 19, from which both claims depend, infers that the coating must be on the outside of the tubing, while claims 26 and 37 require the coating to be on the inside of the tubing. Claim 19 has been amended to clarify that the cell barrier coating is coated on at least one surface to prevent body cells from breaking down the base material. Claim 26 has been amended to clarify that the tubing also includes an inner surface that defines the interior of the tubing and that the barrier coating covers the inner surface. Claim 37 has been amended to clarify that the second layer of the improving means covers the base material tubing within and without. In view of these clarifying amendments, the Examiners of claims 26 and 37 under 112, second paragraph, should be withdrawn.

Finally, the Examiner has further rejected claims 19-23, 25-29, 31, 33, 35-37, 41 and 42 under 35 U.S.C. §102(b) as being anticipated by Kuyava (WO

01/67966 A2), claims 24, 30, 32, 34, 38 and 39 under 35 U.S.C. §103 as being unpatentable over Kuyava alone, and claim 40 also under §103, as being unpatentable over Kuyava in view of Timm (USP 4,517,967). The Examiner's rejections are respectfully traversed.

For a claimed invention to be anticipated by a prior art reference, every element of the claim must be disclosed in the reference. For a claimed invention to be obvious over a combination of references, there must be some reason for one of ordinary skill in the art to have combined the references to produce the claimed invention. Here, the claimed invention of the present application is neither anticipated by Kuyava nor obvious over Kuyava in combination with Timm because the primary cited reference, Kuyava, does not disclose or suggest all of the limitations of the claimed invention recited in the rejected claims.

With regard to the Examiner's rejection of claims 19-23, 25-29, 31, 33, 35-37, 41 and 42 under 35 U.S.C. §102(b) as being anticipated by Kuyava, independent claim 19 of the present application has been amended to recite (1) that the claimed implant is further comprised of property improving means for improving at least one physical property of the implant, other than self-supporting and cell barrier properties, with the property improving means being comprised of a core of viscoelastic material covered with a base material of silicone, and (2) that

the barrier coating is comprised of a poly-para-xylylene polymer or a biocompatible metal coating. New independent claim 44 recites these same features. New independent claim 51 recites that the claimed implant is further comprised of property improving means for improving at least one physical property of the implant, other than self-supporting and cell barrier properties, and that the base material forms a first layer and that the property improving means comprises a second layer applied on the first layer, with the second layer being more fatigue resistant than the first layer. New independent claim 51 also describes the second layer as being comprised of a polyurethane layer.

Kuyava does not anticipate amended independent claim 19 and new independent claim 44 because Kuyava does not disclose an implant with property improving means comprised of a core of viscoelastic material covered with a base material of silicone or a barrier coating comprised of a biocompatible metal coating.

Kuyava also does not anticipate new independent claim 51 because Kuyava does not disclose a base material comprised of silicone and a property improving means comprised of polyurethane that coats the silicone or a barrier coating comprised of a biocompatible metal coating.

Kuyava purports to disclose a penile prosthesis that includes components formed from silicone or similarly flexible material which are coated with a material that increases the strength of the component while also reducing its coefficient of friction. In a preferred embodiment of his prosthesis, both the inner and outer surfaces of the tube(s) of the cylinder used to form the prosthesis are coated with a very thin layer of parylene so that one surface of the cylinder slides smoothly against another surface to diminish wear due to abrasion and to minimize fatigue and resist contact stresses. In this regard, Kuyava teaches that “[p]arylene is an ideal material for this purpose in that it provides a very strong and wear resistant surface, is relatively slippery, is fatigue resistant, and allows for repeated expansion and contraction with no negative effects.” Kuyava is not concerned with reducing degradation of an implant, such as a penile prosthesis, caused by body cells breaking down the material used to make the implant.

Given that amended independent claim 19 is not anticipated by Kuyava, dependent claims 24-26, 29 and 31-43, which depend directly or indirectly from claim 19, are also not anticipated by Kuyava. Similarly, because new independent claims 44 and 51 are not anticipated by Kuyava, dependent claims 44-48 and 50 and 51, which depend directly or indirectly from such claims, are also not anticipated by Kuyava.

With regard to the Examiner's rejection of claims 24, 30, 32, 34, 38, 39 and 40 under 35 U.S.C. §103(a), given the deficiencies in Kuyava discussed above, such claims are not obvious over Kuyava. The Examiner's citation of Timm (USPN 4,517,967) in combination with Kuyava in his rejection of claim 40 under §103 as teaching the use of PTFE for penal implants as being old and well known in the art does not compensate for the noted deficiencies in Kuyava discussed above, and, thus, claim 40 is not obvious over the combination of Kuyava and Timm, as argued by the Examiner.

Claims 24, 30, 32, 34, 38 and 39 are also not obvious, under §103, over Kuyava and what the Examiner contends is "old and well known in the art" or "commercially available" and therefore obvious, because the Examiner has failed to provide concrete factual evidence to support his §103(a) determination that the claims are not patentable.

The Federal Circuit has held that an examiner, when making factual findings for a §103(a) patentability determination of a claimed invention, must rely on "concrete factual evidence" to support a rejection of the claimed invention. *See In re Zurko*, 258 Fed.3d 1379, 1385-86 (Fed. Cir. 2001).

In *Zurko*, the claimed invention was directed to a method for more efficiently creating a secure or "trusted" computer environment. The Examiner

rejected the claimed invention under 35 U.S.C. §103, relying on a combination of two prior art references, *i.e.*, the UNIX Operating System ("UNIX") and a program (Dunford, FILER Version 2.20 ("FILER 2")) for repeating potentially dangerous commands before execution. In sustaining the rejection, the Patent Office Board of Appeals" contended that even if the cited UNIX and FILER 2 references did not disclose a trusted path, 'it is basic knowledge that communication in trusted environments is performed over trusted paths' and, moreover, verifying the trusted command in UNIX over a trusted path is 'nothing more than good common sense.'" Zurko, 258 F.3d at 1385. On appeal, the Federal Circuit rejected the Board's contentions, holding:

This assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidence support. As an administrative tribunal, the Board clearly has expertise in the subject matter over which it exercises jurisdiction. This expertise may provide sufficient support for conclusions as to peripheral issues. With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.

Zurko, 258 F.3d at 1385-86. (Emphasis added). The same is true with respect to the Examiner's rejection of claims 24, 30, 32, 34, 38 and 39 under

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§103(a) as being obvious over Kuyava. Thus, it is not proper for the Examiner to rely on his assertions of what is “old and well known in the art” or “commercially available” and therefore obvious to support his §103(a) rejection of claims 24, 30, 32, 34, 38 and 39 under §103(a). Rather, the *Zurko* decision requires the Examiner to provide concrete factual evidence to support his determination that claims 24, 30, 32, 34, 38 and 39 are not patentable because they are obvious over the cited Kuyava reference in combination with what the Examiner asserts is “old and well known in the art” or “commercially available” and therefore obvious.

In view of the foregoing, it is believed that all of the claims pending in the application, *i.e.*, claims 19, 24-26, 29 and 31-71, are now in condition for allowance, which action is earnestly solicited. If any issues remain in this

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application, the Examiner is urged to contact the undersigned at the telephone
number listed below.

Respectfully submitted,

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From Wikipedia, the free encyclopedia
(Redirected from Teflon)

PTFE is a fluorocarbon solid, as it is a high molecular weight compound consisting wholly of carbon and fluorine. Fluorocarbons are not as susceptible to the London dispersion force (van der Waals force) due to the high electronegativity of fluorine. Therefore, water and water-containing substances, and oil and oil-containing substances, like most foods do not wet PTFE, as adhesion to PTFE surfaces is inhibited. Due to this property PTFE is used as a non-stick coating for pans and other cookware. It is very non-reactive, partly because of the strength of carbon–fluorine bonds and so it is often used in containers and pipework for reactive and corrosive chemicals. Where used as a lubricant, PTFE reduces friction, wear and energy consumption of machinery.

- 1 History
- 2 Properties
- 3 Safety
 - 3.1 Carcinogens in production
- 4 Similar polymers
- 5 See also
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- 7 References
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PTFE was accidentally invented by Roy Plunkett of Kinetic Chemicals^[1] in 1938.^[2] While Plunkett was attempting to make a new CFC refrigerant, the perfluoroethylene polymerized in its pressurized storage container. (In this original chemical reaction, iron from the inside of the container acted as a catalyst.) Kinetic Chemicals patented it in 1941 and registered the Teflon trademark in 1944.^[3] The original patent number is US2,230,654.^[4]

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